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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/679,378	10/07/2003	David Carlson	39147-0016	4289

26633 7590 04/20/2005

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EXAMINER	
CHUNDURU, SURYAPRABHA	
ART UNIT	PAPER NUMBER
1637	

DATE MAILED: 04/20/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/679,378	CARLSON ET AL.	
	Examiner	Art Unit	
	Suryaprabha Chunduru	1637	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *07 October 2002*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *07 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Status of Application

1. Claims 1-20 are currently pending. Claims 1-20 are considered for examination in this office action.

Priority

2. This application filed on October 7, 2003 claims benefit of US provisional 60/416,228 filed on 10/07/2002.

Claim interpretation

3. In the instant specification, the "stabilizing agent" is described as a reagent that stabilizes the solution and stabilizes the DNA that is extracted from the source tissue or material, a chelating agent is defined as any composition that is effective for chelating metal ions and buffering agent as an agent that can act as a pH buffer (see page 6, line 5-23). Thus, in the light of the instant specification, the broad terms a stabilizing agent, a chelating agent and a buffering agent are given the broadest reasonable interpretation and thus a surfactant or detergent (triton-X-100 or sodium diodecyl sulfate (SDS)) is interpreted as a stabilizing agent, EDTA is interpreted as a chelating agent and potassium iodide or tris (hydroxymethyl) aminomethane (Tris) as a buffering agent.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

A Claims 1, 13-18 are rejected under 35 U.S.C. 102(a) as being anticipated by Elliott (USPN. 6,316,248).

Elliott teaches a method of claim 1, for extracting DNA from a biological sample, comprising contacting the sample with a highly basic solution (pH 8.0) comprising an effective concentration of a chelating agent (4ml of EDTA), an effective concentration of a stabilizing agent (20 ml of 20% sodium diodecyl sulfate), and an effective concentration of a buffering agent (2M of tris(hydroxymethyl)aminomethane (Tris)) (see col. 1, line 52-64, col. 2, line 1-8, line 54-63).

With regard to claim 13-14, Elliott teaches that said sample comprises human hair (see col. 2, line 26-63);

With regard to claim 15, Elliot teaches that the hair is not ground prior to extraction (see col. 1, line 52-55, col. 2, line 54-65, indicates that the hair is not ground, instead it is directly incubated in said DNA liberating solution);

With regard to claims 16-18, Elliot teaches that the sample comprises biological sample on a solid matrix paper, that is, a FTA paper (see col. 2, line 16-51). Thus the disclosure of Elliot meets the limitations in the instant claims.

B. Claims 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Boom et al. (USPN. 5,234,809).

Boom et al. a method of claim 1, for extracting DNA from a biological sample, comprising contacting the sample with a highly basic solution (lysis buffer L6) comprising an effective concentration of a chelating agent (0.2M EDTA), an effective concentration of a stabilizing agent (2.6 g of triton-X-100), and an effective concentration of a buffering agent (12.45 g potassium iodide comprising buffer or L2 buffer) (see col. 7, line 6-23, col. 8, line 14-35). Thus the disclosure of Boom et al. meets the limitations in the instant claim 1.

C. Claims 1, 16-20 are rejected under 35 U.S.C. 102(b) as being anticipated by Fomovskaia et al (WO 00/62023).

Fomovskaia et al. teach a method of claim 1, for extracting DNA from a biological sample, comprising contacting the sample with a highly basic solution comprising an effective concentration of a chelating agent (EDTA), an effective concentration of a stabilizing agent (5-10% sodium diodecyl sulfate), and an effective concentration of a buffering agent (tris (hydroxymethyl)aminomethane (Tris)) (see page 8, line 1-7 of paragraph 2, page 10, line 1-8 of paragraph 3, page 11, line 1-4, paragraphs 1-2).

With regard to claims 19-20, Fomovskaia et al. teach that said sample comprises blood (see page 13, line 1-3 of paragraph 1, page 20, paragraph 1 under example 1);

With regard to claim 16-18, 20, Fomovskaia et al. teach that the sample comprises a biological sample on a solid matrix paper, that is, a FTA paper (see page 19, line 1-2 of paragraph 1, page 20, paragraph 1 under example 1);

Thus the disclosure of Fomovskaia et al. meets the limitations in the instant claims.

D. Claims 1, 13-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Elliott (USPN. 6,316,248).

Elliott teaches a method of claim 1, for extracting DNA from a biological sample, comprising contacting the sample with a highly basic solution (pH 8.0) comprising an effective concentration of a chelating agent (4ml of EDTA), an effective concentration of a stabilizing agent (20 ml of 20% sodium diodecyl sulfate), and an effective concentration of a buffering agent (2M of tris(hydroxymethyl)aminomethane (Tris)) (see col. 1, line 52-64, col. 2, line 1-8, line 54-63).

With regard to claim 13-14, Elliott teaches that said sample comprises human hair (see col. 2, line 26-63);

With regard to claim 15, Elliot teaches that the hair is not ground prior to extraction (see col. 1, line 52-55, col. 2, line 54-65, indicates that the hair is not ground, instead it is directly incubated in said DNA liberating solution);

With regard to claims 16-18, Elliot teaches that the sample comprises biological sample on a solid matrix paper, that is, a FTA paper (see col. 2, line 16-51). Thus the disclosure of Elliot meets the limitations in the instant claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any

evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 2-12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Elliott (USPN. 6,316,248). in view of Swason et al. (USPN. 4, 548,608) and Rieck (USPN. 4,664,839).

Elliott teaches a method of claim 1, for extracting DNA from a biological sample, comprising contacting the sample with a highly basic solution comprising an effective concentration of a chelating agent, an effective concentration of a stabilizing agent, and an effective concentration of a buffering agent (see col. 1, line 52-64, col. 2, line 1-8, line 54-63).

However, Elliott did not specifically teach, alkali metal gluconate salt (sodium gluconate), alkali metal silicate salt (sodium silicate) and alkali metal phosphate (sodium phosphate).

Swanson et al. teach a composition for depilating hair, said composition comprises sequestering agents (includes chelating agents and stabilizing agents), wherein said composition comprises predetermined concentrations of sodium gluconate, sodium silicate and sodium phosphate (see col. 2, line 38-52); Swanson et al. also teach that the sodium phosphate due to its buffering ability maintains the high pH (pH-13) thus extending an alkaline contact time with disulfide bonds of protein in the biological sample and sodium gluconate acts as a chelating agent (see col. 3, line 14-39); the composition is formulated to achieve loosening of the biological material and recovery of protein (see col. 3, line 14-68).

Rieck teaches use of crystalline layered sodium silicates, wherein Rieck discloses that sodium silicate acts as a washing agent (detergent) and functions as a supplier of Na^+ ions and increase the pH value and also disclose the molar concentrations of the sodium silicates that facilitate the function of a detergent (see col. 1, line 55-63).

It would have been prima facie obvious to a person of ordinary skill in the art at the time the invention was made to modify the method for extracting DNA as taught by Elliott with a step of including alkali metals as chelating, stabilizing and buffering agents as taught by Swanson et al. and Rieck for the purpose of increasing alkalinity or pH of the solution to promote alkaline lysis because Swanson et al. explicitly taught that sodium phosphate due to its buffering ability stabilizes the high pH (pH-13) thus extending an alkaline contact time with disulfide bonds of protein in the biological sample and sodium gluconate acts as a chelating agent (see col. 3, line 14-39); the composition is formulated to achieve loosening of the biological material and recovery of protein in alkaline solution (see col. 3, line 14-68). Further Rieck taught that the sodiumn silicate supplies Na^+ ions and increase the pH value of the composition (see col. 1, line 55-60). An ordinary artisan would have a reasonable expectation of success that modifying the method of DNA extraction as taught by Elliott with the inclusion of said agents as taught by Swanson et al. and Rieck would result in a highly alkaline solution that would aid in alkaline lysis of DNA in a biological sample.

Further selection of specific concentrations represents routine optimization with regard to the chelating, stabilizing and buffering agents, which routine optimization parameters are explicitly recognized in Elliott and Swanson et al. As noted in *In re Aller*, 105 USPQ 233 at 235,

More particularly, where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. Routine optimization is not considered inventive and no evidence has been presented that the selection of concentration performed was other than routine, that the products resulting from the optimization have any unexpected properties, or that the results should be considered unexpected in any way as compared to the closest prior art.

Conclusion

No claims are allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 571-272-0783. The examiner can normally be reached on 8.30A.M. - 4.30P.M , Mon - Friday,.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Benzion can be reached on 571-272-0782. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Prabha Chunduru 4/15/05
Suryaprabha Chunduru
Examiner
Art Unit 1637